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# 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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| Submitter Name: | Curexo Technology Corp. |
| Submitter Address : | 47320 Mission Falls Court Fremont, CA 94539 |
| Contact Person: | Glen Emelock |
| Phone Number: | (510) 249-2300 |
| Fax Number: | (510) 249-2396 |
| Date Prepared: | January, 2014 |
| Device Trade Name: | DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System |
| Device Common Name: | Stereotaxic Instrument |
| Classification Name: | Orthopedic Computer Controlled Surgical System, OJP, HAW |
| Regulation Number: | 21 CFR 882.4560 |
| Predicate device: | DigiMatch™ ROBODOC® Surgical System, K072629 |
| Reason for submission: | Not previously marketed in the USA |

**Device Description:**
The DigiMatch™ ORTHODOC®/ROBODOC® Encore System is a three-dimensional, graphical, preoperative planner and implementation tool for treatment of patients who require a total hip arthroplasty (THA) procedure. This device is intended as an alternative to manual template planning, broaching, and reaming techniques for the preparation of bone for patients requiring a THA procedure. The system consists of the ORTHODOC® Preoperative Planning Workstation and ROBODOC® , a robotic system composed of an electromechanical arm, electronics control cabinet, computer, display monitor, and miscellaneous accessories such as cutters, drapes, irrigation sets, probes, and markers. ORTHODOC® and ROBODOC® when used according to the instructions for use, make precision bone preparation possible before and during THA surgical procedures..

**Intended Use:**
The DigiMatch™ ROBODOC®/ORTHODOC® Encore Surgical System is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC®/ORTHODOC® Encore Surgical System is indicated for orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

**Predicate Device:**
The DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System is substantially equivalent to the DigiMatch™ ROBODOC® Surgical System, K072629.

**Comparison of Technological Characteristics and Principles of Operation:**
The DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System is similar to the legally marketed device listed previously in that they share the same intended use and indications, technological characteristics, principles of operation and performance data as the predicate device.

Table 1 provides a comparison of technological characteristics and principles of operation between the DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System and its predicate device.

**Table 1: Comparison of Technological Characteristics and Principles of Operation**

| Device | Patient Image Data | Presurgical Plan | Surgical Plan Data | Machine Instructions | Patient/Robot Registration Requirement | Robot Electromechanical Arm |
|---|---|---|---|---|---|---|
| DigiMatch™ ROBODOC® Surgical System | Yes, CT Scan | Yes, Presurgery | Yes, high level operative plan | Yes, Robotic Arm driven by validated control software and hardware | Yes, point to surface registration | Yes, robot with single electromechanical arm and end effector implement control file instructions |
| DigiMatch™ ROBODOC®/ ORTHODOC® Encore Surgical System | Yes, CT Scan | Yes, Presurgery | Yes, high level operative plan | Yes, Robotic Arm driven by validated control software and hardware | Yes, point to surface registration | Yes, robot with single electromechanical arm and end effector implement control file instructions |

Any minor differences between the DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System and its predicate device raise no new questions of safety or effectiveness nor change the device's intended therapeutic effect in comparison to its predicate.

**Performance Data:**
The DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System has been evaluated with non-clinical performance testing for the following modifications and or improvements:

- ORTHODOC® host computer and operating system
- ORTHODOC® addition of CT file complete/size check
- ORTHODOC®/ROBODOC® elimination of pin patient/robot registration
- ORTHODOC®/ROBODOC® THA/TKA (non-USA only) factory setting
- ROBODOC® Two-Pin Registration Recovery
- Osteotomy demarcation
- ROBODOC® electromechanical arm
- ORTHODOC®/ROBODOC® error message colors
- ROBODOC® bearing sleeve
- ROBODOC® Smart Bone Motion Monitor (BMM)
- ROBODOC® Percutaneous Probe
- Change of Irrigation Set Length and Manufacturer

Bench and simulated use tests included functional software testing for the ORTHODOC® Surgical Planning Workstation hardware, software, and user interface, and hardware, functional software, user interface, instrument/tool and sterile disposable accessory testing and simulated clinical use of new and changed instrument/tools for the DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System.

**Conclusion**
In conclusion, based on the intended use, indications for use, technological characteristics, and performance data, the DigiMatch™ ORTHODOC®/ROBODOC® Encore Surgical System is substantially equivalent (SE) to the DigiMatch™ ROBODOC® Surgical System, K072629 predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 27, 2014

Curexo Technology Corporation
% Glen Emelock
The CRO Group, Incorporated
32 Harrison Street
Melrose, Massachusetts 02176

Re: K140038
Trade/Device Name: DigiMatch™ ORTHODOC® ROBODOC® Encore Surgical System
Regulation Number: 21 CFR 882.4560
Regulatory Class: Class II
Product Code: OJP, HAW
Dated: February 25, 2014
Received: February 26, 2014

Dear Mr. Emelock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

***510(k) Number:*** K140038

***Device Name***: DigiMatch™ ORTHODOC® / ROBODOC® Encore Surgical System

***Indications For Use***:
The DigiMatch™ ROBODOC®/ORTHODOC® Encore Surgical System is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC®/ORTHODOC® Encore Surgical System is indicated for orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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